REMARKS

Reconsideration of the above-identified application is respectfully requested.

Claims 1–13 and 15–21 remain in application. New claim 22 has been added. The claim states that no water is added to the hormone formulation of claim 1. Support for this amendment is found on p. 9, para. 4 beginning "water-free formulation." No new subject matter has been added to the application.

In view of the Office Action Response dated February 13, 2008, and Request for Continued Examination dated April 14, 2008, the Examiner is maintaining the previous rejection. In the noted Response, Applicant argued that the Illum reference does not teach the recited concentration or lipophilic nature of the composition and that the only complete system formulated by Illum is one that contains albumin. The Examiner noted that the Illum reference at col. 7, ll. 47–49 states that gelatin microspheres contain 90% olive oil and therefore fall within Applicant's claimed range of lipophilic carriers.

New claim 22 has been added because the prior art references require the addition of water to form an emulsion.

Claims 1–6, 8, 13, 15–17, and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Illum in view of the Ko et al. reference.

The Illum reference requires the use of additional water for the preparation of gelatin microspheres. The unnamed active agent is then incorporated into the microspheres or sorbed into/onto the system after preparation. The Illum reference describes various gelatin systems that involve the use of water for formation of the gel. For example, at col. 6, ll. 20-34, starch microspheres are formed by dissolving potato starch in water in one solution and admixing in a second of polyethylene glycol in water. Heat is applied with stirring to form an emulsion, which is then cooled and converted to gel particles. At col. 6, ll. 47-62, albumin microspheres are

formed by mixing purified olive oil with petroleum ether and stirring. To this mixture, an aqueous solution of rabbit serum albumin is added with other ingredients and upon freeze drying, microspheres are formed. Further, at col. 7, ll. 26–31, 10% bovine gelatin is mixed with a 30% solution of PEG until coacervation is reached. The mixture is then cooled on ice with constant stirring wherein microspheres are isolated and freeze dried. In another example at col. 7, ll. 37–46, chitosan is dissolved in water at a concentration of 5%. Soybean oil is mixed with a small portion of the chitosan to form a water-in-oil emulsion. Microspheres of this emulsion are stabilized with glutaraldehide under continual stirring. The resultant microspheres are isolated, centrifuged, and freeze dried. As previously stated, the active agent is incorporated into the microspheres during formulation of the microspheres or sorbed into/onto the system after preparation.

The various disclosures of the formation of different types of gel in the Illum reference require the addition of water for the gel formation. Water is not required in new claim 22 of the instant invention. The claims are therefore patentable over the cited references and the rejection.

Further, water is not added in the formulation of claim 1 – step (c) for it states the formulation includes a compound or mixture of compounds having surface tension reducing activity in an amount in *situ* generation of an emulsion upon contact with water. The water is present in the nasal passages.

The Ko et al. reference also requires the addition of water while formulating oil-in-water emulsions. At p. 199, second paragraph, entitled "Preparation of Formulations," three differently charged emulsion formulations are prepared by first formulating an o/w emulsion containing one gram Span 80, one gram testosterone, and 40 grams neutralized soybean oil dispersed in an aqueous phase of 50 gram phthalate buffer solution at pH 5.5 containing two grams Tween 80.

The solution was subsequently treated to form positively, negatively, and neutrally charged submicron emulsion formulations, respectively. Applicant's claimed invention does not require the formation of three types of emulsion formulations nor the addition of water to form an emulsion in new claim 22. The claim is patentable in view of the Illum reference and the Ko et al. reference whether taken singly or in combination. Therefore, the rejection should be withdrawn.

Claim 7 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Illum reference in view of the Ko et al. reference and further in view of the Patel et al. reference.

The Patel et al. reference is directed to a solid dosage form for a wide variety of pharmaceutical compounds. Typically, the solid pharmaceutical compound includes a solid carrier and the carrier includes a substrate and an encapsulation coating of the substrate. The coating may include different combinations of pharmaceutically active ingredients, including triglycerides. Even though hydrophobic ingredients can be utilized, as described at col. 4, ll. 58-63, the hydrophobic ingredients may contain water in small amounts, possibly less than 1% by weight. In addition, at col. 40, ll. 52-53, solvents are identified as an additive to the pharmaceutical composition. The solvents defined include water. While the Patel et al. reference describes non-analogous prior art, a solid pharmaceutical composition, not a liquid composition that may be subject to nasal application, the formulation still contains added water. As stated, added water is not required in the formulation of claim 1 nor claim 22 of the claimed invention. Therefore, the rejection of claim 7 should be withdrawn.

Claims 9-10 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Illum reference in view of the Ko, et al. reference and further in view of the Dondeti reference. The examiner alleges that the Dondeti reference teaches that drugs can be

administered to the nasal cavity in the form of solutions, suspensions, powders, microspheres, gels, or inserts for local or systemic effect at page 119 of the reference. Viscosity modifying agents, according to the examiner, disclosed in the Dondeti reference may be combined with the other references to suggest claim 1 of the present invention. Claim 1 has been defined as not including added water. Claim 22 states that added water is not required in the formulation. The agents listed at page 119 of the Dondeti reference, cited by the examiner, typically contain water, for example, solutions, suspensions and gels. These dosage forms containing water are not claimed currently in applicant's claimed invention. Therefore, the reference, in combination with the other references cannot render obvious the claimed invention. The rejection should be withdrawn.

Claims 1-8, 10-12, 15, 18-19 and 21 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 10-12, 16, 18-21 and 24-25 of copending Application No. 11/560,187. A terminal disclaimer is being submitted herewith to overcome this rejection.

Claim 11 has been rejected under 35 U.S.C. 103 as being unpatentable over the Illum reference and view the Ko et al. reference and further in view of the Glass reference.

The examiner states that the Glass reference provides the teaching of using silicone dioxide as a viscosity increasing agent. The Glass reference contains non-analogous art, a description of a microwavable popcorn product. This reference has no relevance to pharmaceutical products having formulations that can be administered in nasal cavities. Any teaching from this reference is not relevant to the claimed invention, nor does it provide any of the missing parts of the teachings of the previously recited references to reject the noted claim.

Therefore, this reference, taken singly in combination with the other references can render obvious the claimed invention.

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (312) 609-7947.

Respectfully submitted,

Date: October 6, 2008

By: _____
John J. Gresens, Reg. No. 33,112

Vedder Price P.C.
222 N. LaSalle St., Suite 2600
Chicago, Illinois 60601
phone: (312) 609-7947
fax: (312) 609-5005